

Exhibit 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CARDINAL HEALTH, INC.,

Plaintiff,

v.

ERIC H. HOLDER, JR., et al.,

Defendants.

No. 1:12-cv-00185-RBW

PLAINTIFF CARDINAL HEALTH, INC.'S REPLY
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Cardinal Health, Inc. (“Cardinal Health”) is committed to preventing diversion of controlled substances. In 2007, DEA launched an initiative that focused on distributors and their controls to detect and prevent diversion, principally involving “rogue” Internet pharmacies. Several distributors, including Cardinal Health, had distribution centers suspended from selling controlled medicines while they enhanced their diversion-control systems. Cardinal Health took responsibility and recognized that it needed to improve its control systems for identifying and reporting suspicious orders by pharmacies and preventing diversion. Through investment, innovation, and training, Cardinal Health built a real-time monitoring program that is robust. In a little over three years, Cardinal Health has terminated sales of controlled substances to at least 315 pharmacies nationwide and 149 pharmacies in Florida. In this respect, Cardinal Health has been far more rigorous than the DEA, which suspended the registrations of only a fraction of these pharmacies, despite receiving notice from Cardinal Health of each termination. DEA’s own statistics reveal that Cardinal Health’s efforts are effective: The average amount of oxycodone distributed by Cardinal Health’s Lakeland Distribution Center (“Lakeland”) to its Florida pharmacy customers is about half the amount of oxycodone purchased by the average Florida pharmacy. *See* Opp., Att. 4 at 4.

In its ISO, DEA singles out four of the Lakeland facility’s approximately 2,700 customers—the top four purchasers of oxycodone. For each, the ISO sets forth Cardinal Health’s aggregate sales of oxycodone over the nearly four-year period from January 1, 2008, through late 2011. Based on these numbers alone, the ISO asserts that Cardinal Health has failed to maintain effective controls to prevent diversion. In its opposition brief and the declaration of Joseph Rannazzisi, DEA argues at length that Cardinal Health should have done more to ascertain whether DEA-registered doctors were writing illegitimate prescriptions that were filled

by these four DEA-registered pharmacies. Whether DEA is right is a question that will be decided in an administrative hearing before the DEA. It is not a question before this Court.

Congress made clear in the Controlled Substances Act (“CSA”) that DEA may wield the ultimate weapon of an ISO—and immediately suspend a registrant without notice or an opportunity to be heard—only in exigent circumstances, when necessary to prevent “imminent danger to the public health or safety.” 21 U.S.C. § 824(d). That standard, which is also constitutionally mandated to ensure due process, is plainly not met here. DEA cannot dispute that Cardinal Health terminated sales to two of the four pharmacies named in the ISO (Gulf Coast and Caremed) months before the ISO issued and even before DEA served its Administrative Inspection Warrant (“AIW”) on Cardinal Health. The company—out of an abundance of caution—has also now suspended sales of controlled substances to the other two pharmacies named in the ISO (the two CVS Sanford pharmacies). That suspension, which occurred the day the ISO was served, was consistent with Cardinal Health’s assurance to DEA, well before the ISO, that it would cease distribution of controlled substances to any customer DEA believed was likely engaged in diversion. Even before Cardinal Health suspended the two CVS stores, volumes of oxycodone purchases had dropped meaningfully. In October 2011, CVS stopped filling prescriptions written by 22 doctors that accounted for more than 64% of the oxycodone dispensed by the Sanford stores from May through October 2011. Am. Moné Decl. ¶ 55. Cardinal Health’s distribution of oxycodone to each of these stores decreased by approximately 80% in the last three months compared to the prior three months. *Id.* In light of these events, sales to the four pharmacies named in the ISO cannot support a finding of imminent danger to the public health or safety. Notably, the ISO does not reference any of these points.

DEA now contends (at 25) that its “concerns” are not limited to the four pharmacies

named in the ISO and that it used information about these pharmacies to “make a broader conclusion” about Lakeland’s anti-diversion controls. This explanation did not appear in the ISO, as is required. It is also insufficient to meet the requisite “imminent danger” standard. An upstream distributor such as Cardinal Health does not dispense controlled substances to the public and thus cannot pose any “*imminent*” danger to the public unless it is currently distributing to customers that it knows or should know are engaged in diversion or is itself engaged in the diversion of controlled substances. DEA has identified no such customer. DEA also has not alleged that any controlled substance left the closed system of distribution while in Cardinal Health’s possession. Further, the DEA itself contends (at 18) that Cardinal Health shipped significantly more oxycodone to its top four customers than to its other Florida retail customers. As a result, there is no basis for using the four pharmacies identified in the ISO as a proxy. Stores that allegedly accounted for such a disproportionate amount of Cardinal Health’s sales of oxycodone cannot reasonably be considered representative of the risk posed by Cardinal Health’s *current* customer pool—which is what matters for “imminent” danger purposes.

DEA’s own delay in pursuing this matter confirms that Cardinal Health’s continued registration—for the time required to adjudicate the matter before the DEA—poses no imminent danger. The ISO relies on sales of oxycodone in 2008, 2009, 2010, and 2011. Alleged conduct dating back years, however, even if potentially relevant to an Order to Show Cause (“OSC”), obviously cannot credibly be said to pose an *imminent* danger. The ISO relies almost entirely on aggregate sales data that Cardinal Health reports to DEA each month. *See* Am. Moné Decl. ¶ 35. If DEA believed those data demonstrated imminent harm, it could have and should have acted sooner. Moreover, DEA waited over three months after serving its AIW to serve the ISOs, yet the ISO recites no new factual information and, importantly, fails to consider material changes

since October 2011. The timing of DEA's action thus suggests that it is calculated more to punish than to protect.

Recognizing that the harm alleged in the ISO cannot sustain the suspension, DEA has now attempted to offer new and lengthy *post hoc* rationalizations for its action. These rationalizations are both irrelevant and deficient. Bedrock principles of administrative law, the CSA, and DEA's own regulations mandate that the necessary reasoned basis for issuing an ISO be set forth in the ISO itself—not in a record developed by the DEA's lawyers and enforcement personnel after the fact in adversarial litigation. DEA contends that it could issue an ISO—and strip Cardinal Health of its registration—by simply “put[ting] Cardinal on notice of its concerns” and providing a “summary” of its decision. Opp. at 25; *see also id.* at 13. But DEA's own regulation that governs ISOs—which the DEA does not acknowledge in its brief—requires precisely what the DEA has failed to provide in this case: “*findings* [by the Administrator] regarding the danger to public health or safety.” 21 C.F.R. §1301.36(e) (emphasis added). It is also well settled as a matter of administrative law that where an agency provides a “contemporaneous explanation of [its] decision ... [t]he validity of the [agency's] action must ... stand or fall on the propriety of th[e] finding[s]” that appear in the decision. *Camp v. Pitts*, 411 U.S. 138, 142, 93 S. Ct. 1241, 1244 (1973).

DEA's *post hoc* rationalizations also fail on their own terms. None of the deficiencies asserted by DEA demonstrates that Cardinal Health's continued registration poses a current danger to public health or safety. DEA's allegations relate almost entirely to the four pharmacies named in the ISO. But as discussed above, Cardinal Health no longer distributes controlled substances to those pharmacies. Reliance by DEA on past allegations of misconduct relating to sales to “rogue” Internet pharmacies—settled by Cardinal Health and DEA in the 2008

Settlement and Release Agreement and Administrative Memorandum of Agreement (“MOA”)—are even further afield. The allegations in the current ISO involving sales to legitimate pharmacies like CVS bear no relationship to the past allegations, which (contrary to DEA’s assertion) were disclosed to the Court. *See infra* p. 16. Indeed, DEA’s *post hoc* contentions are in many respects inaccurate, incomplete, or misleading. The Court need not resolve the parties’ disputes about actions previously taken by Cardinal Health. That can be debated at the administrative hearing. A sampling of DEA’s inaccuracies, however, is provided below and in the Supplemental Declaration of Michael Moné.

For all of these reasons, Cardinal Health is likely to succeed on the merits of its challenge to the ISO. It also readily satisfies the other preliminary injunction requirements. The ISO threatens to prohibit all distributions of controlled substances from Cardinal Health’s Lakeland facility. The closure of that facility will cause disruption in the supply of important drugs to hospitals and pharmacies serving critically ill patients throughout Florida. Facing these disruptions, customers will leave Cardinal Health and shift their purchases toward other companies. The aggregate harm to Cardinal Health from suspensions in 2007 is estimated to have been approximately \$1 billion in lost revenues on an annualized basis. The ISO also would impose significant reputational harm and loss of goodwill. And it would cause increased but difficult-to-calculate expense as Cardinal Health struggles to re-route shipments from other facilities. Because sovereign immunity would bar recovery, this harm is not only significant but also irreparable. By contrast, DEA would suffer no harm from issuance of an injunction. It would simply be required to follow its ordinary procedures for seeking to revoke a registration. DEA may not like the limitation on its ISO power imposed by the CSA, but that is not cognizable injury. Finally, the public interest favors an injunction because the ISO threatens to

disrupt the availability of important medication to patients in need—a consequence DEA simply ignores, despite its dual mission to fight diversion and ensure an adequate supply of medicines.

ARGUMENT

I. CARDINAL HEALTH IS LIKELY TO SUCCEED ON THE MERITS

A. The ISO Can Be Sustained Only If The Administrator Reasonably Found—And The Court Concludes—That Continued Registration Of Cardinal Health Would Pose An Imminent Danger

DEA may issue an ISO—without providing a registrant with prior notice or an opportunity to respond to DEA’s allegations—*only* if the Administrator actually “*finds*” that continued registration poses an “*imminent danger* to the public health or safety.” 21 U.S.C. §824(d) (emphasis added). Such a finding is mandated not only by the statute but also by the Constitution. Due process rights are at stake when a DEA registration is suspended or revoked. *See Harline v. DEA*, 148 F.3d 1199, 1204 (10th Cir. 1998); *Novelty Distributing, Inc. v. Leonhart*, 562 F. Supp. 2d 20, 30 (D.D.C. 2008) (noting “the property interests of distributors” in their registrations). Absent an imminent danger, there is no basis for depriving a registrant of its procedural safeguards against erroneous deprivation. *See Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S. Ct. 893 (1976); *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 62, 114 S. Ct. 492, 505 (1993) (“To establish exigent circumstances, the Government must show that less restrictive measures ... would not suffice to protect the Government’s interests”). To be “imminent,” a danger must be “about to occur.” *See The American Heritage College Dictionary*, at 693 (4th ed. 2002). Accordingly, concerns about merely past conduct—though sufficient to initiate a show-cause proceeding, 21 U.S.C. §824(a),(c)—do not provide a proper basis for an ISO, which must serve a quintessentially protective and non-punitive function.

DEA’s extraordinary claim that it can deprive a registrant of its rights through an ISO by merely “put[ting it] on notice of its concerns” is unfounded. Opp. 25 (citing 21 C.F.R.

§ 1301.37(c)). DEA purports to find support in its regulations, *id.*, but the regulation it cites says nothing about ISOs. Rather, it provides that “[t]he *order to show cause* shall ... contain ... a *summary* of the matters of fact and law asserted.” 21 C.F.R. § 1301.37(c) (emphasis added). By contrast, the regulation that actually governs the issuance of ISOs—a regulation that the government omits from its brief—quite sensibly provides that “an *order of immediate suspension* ... shall contain a statement of [the] *findings* regarding the danger to public health or safety.” *Id.* § 1301.36(e) (emphasis added).

DEA is also incorrect (at 15-16) in asserting that its “imminent danger” determinations need only be reviewed for reasonableness. While DEA’s determination must be supported by reasoned explanation at the time of decision under the APA, the “imminent danger” standard is *also* a due process floor. *See supra*. Thus, after satisfying itself that the agency provided a reasonable explanation, the Court must also conclude that a need for emergency intervention actually exists. *See J.J. Cassone Bakery, Inc. v. NLRB*, 554 F.3d 1041, 1044 (D.C. Cir. 2009) (“[I]n contrast with other aspects of [the agency’s] decision, which we review deferentially, ‘a reviewing court owes no deference to the agency’s pronouncement on a constitutional question.’” (internal citation omitted)).

B. DEA Cannot Meet Its Burden Of Showing Imminent Danger Because Cardinal Health No Longer Distributes Controlled Substances To The Pharmacies Named In The ISO

DEA concedes that Cardinal Health no longer distributes controlled substances to any of the four stores that DEA identifies (in the ISO and in its brief) as potential sources of diversion. Further, DEA has identified no other Cardinal Health customer that poses an undue risk of diversion. And, for good reason, DEA has never suggested that Cardinal Health itself is engaging in diversion. These undisputed facts are fatal to DEA’s claim that Cardinal Health poses an *imminent* threat to public health or safety. That Cardinal Health has ceased distributing

to these pharmacies (and to *hundreds* of other pharmacies that DEA disregards) demonstrates, moreover, the seriousness of Cardinal Health's pledge to suspend controlled substance shipments to any pharmacy the agency identifies as an undue diversion risk. DEA disputes these points, but none of its arguments has merit.

First, DEA suggests Cardinal Health's efforts "occurred only after ... DEA issued its investigative warrant." Opp. 27. DEA does not, however, dispute that Cardinal Health ceased distributing controlled substances to two of the four pharmacies DEA identified in the ISO *before* DEA issued the warrant and months before the ISO. *Compare* Moss Decl., Ex. J (Oct. 25, 2011 DEA Warrant); Moss Decl., Ex. A (Feb. 2, 2012 ISO), *with* Am. Mone Decl. ¶42 (Gulf Coast terminated Oct. 5, 2011; Caremed terminated Sept. 26, 2011). And DEA virtually ignores the more than 315 customers nationwide and more than 149 pharmacies in Florida to which Cardinal Health has ceased distributing since January 1, 2009 *because* Cardinal Health concluded those customers posed an unacceptable risk of diversion. Am. Moné Decl. ¶23; *contra* Opp. 30 n.14 (speculating that Cardinal Health may have ceased distributing to these pharmacies for "other unrelated reasons"). In any event, regardless of why Cardinal Health suspended distributions to the four pharmacies named in the ISO, the fact that they no longer receive controlled substances from Cardinal Health means that the company's prior links to the pharmacies cannot support a reasonable inference of *imminent* danger.

Second, DEA questions (at 30) Cardinal Health's pledge to suspend controlled substance shipments to any pharmacy DEA identifies as posing an undue risk of diversion. But Cardinal Health has cut off hundreds of customers, including the two named retail independent pharmacies, even without DEA's help. *See supra*. Moreover, consistent with its *pre*-ISO pledge, Cardinal Health suspended distribution of controlled substances to the remaining two

pharmacies the very day DEA made clear that it considered these pharmacies at risk of diversion—before Cardinal Health even knew that DEA intended to serve ISOs on those pharmacies. To the extent there is an obstacle to Cardinal Health’s pledge, that obstacle comes from DEA, not Cardinal Health. On October 27, and again on December 22, Cardinal Health requested that DEA inform it of the identity of any Cardinal Health customer that the agency believed was likely engaged in diversion. *See* Moss Decl., Exs. C, D. But DEA rejected Cardinal Health’s requests. Am. Mone Decl. ¶35.

Third, DEA dismisses Cardinal Health’s decision to suspend the CVS pharmacies on the theory that it was not before the agency. Opp. 26-27. But even assuming that the Court should ignore this fact, at the time of the Cardinal Health ISO, DEA already knew it would be immediately suspending the CVS pharmacies’ registration. *Id.* at 27 n.11. The Administrator signed the two CVS ISOs and the Cardinal ISO on the same day, *compare* Moss Decl., Ex. A, with Opp., Att. 21 (CVS # 219 and # 5195 ISOs), and DEA “coordinate[d]” service of all three ISOs to occur back to back, Rannazzisi Decl. ¶82.¹ Moreover, given Cardinal Health’s *pre*-ISO pledge, DEA knew that it could stop shipments to those pharmacies by simply telling Cardinal Health that it believed these two stores were likely diverting controlled substances. Additionally, in October 2011, CVS stopped filling prescriptions written by 22 doctors that accounted for more than 64% of the oxycodone dispensed by the Sanford stores from May through October 2011. Am. Moné Decl. ¶ 55. As a result, Cardinal Health’s distribution of oxycodone to these stores

¹ Accepting this analysis would not, as DEA suggests, “thwart DEA’s ability to undertake a concerted enforcement effort against a distribution chain where multiple parties have inadequate controls.” Opp. at 27 n.11. DEA can immediately suspend multiple parties along a distribution chain so long as each party’s continued registration poses an actual, imminent threat to public health and safety. Of course, DEA cannot issue an ISO to *punish* registrants for past acts or to send a message of *deterrence* to other registrants. But it is the Constitution and the statute itself that impose those constraints, not Cardinal Health.

decreased by approximately 80% in the three months before the ISO. *Id.* Accordingly, based only on information in DEA's possession at the time of its decision, the agency could not reasonably have concluded that immediately suspending Cardinal Health was necessary to prevent an imminent threat to public health or safety caused by these two CVS pharmacies.

In any event, DEA certainly knows now that Cardinal Health ceased distributing controlled substances to the Sanford CVS stores on February 3, 2012. Given the due process concerns inherent in ISOs, DEA cannot simply ignore new circumstances that eliminate the alleged basis for imminent danger. *Cf. Gilbert v. Homar*, 520 U.S. 924, 935-36 (1997) (recognizing that the justification for postponing a hearing had diminished as the facts that had justified suspending a public employee without such a hearing changed). Nor is there any reason this Court should not exercise its power to "dissolve[]" the suspension if DEA insists on keeping it in place despite the absence of any danger to the public health and safety. 21 U.S.C. §824(d).

Fourth, DEA argues (at 25) that its "concerns" are not limited to the four pharmacies named in the ISO and that it used information about these four pharmacies to "make a broader conclusion" about Lakeland's anti-diversion controls. As an initial matter, DEA cannot rely on this rationale, which was not articulated in the ISO. *See infra*. In any event, DEA's alleged broader "concerns" cannot support the ISO. Because a wholesaler like Cardinal Health does not prescribe or dispense controlled substances to the public, it cannot pose any *imminent* danger to the public unless it distributes controlled substances to customers it knows (or should know) are engaged in diversion. DEA does not identify any current Cardinal Health customer likely engaged in diversion. And DEA's efforts to highlight the four now-suspended pharmacies named in the ISO undermine its suggestion that Cardinal Health's current customers pose an undue threat. For example, DEA alleges (at 18) that Cardinal Health distributed substantially

more oxycodone to its top four customers than it did to its other customers. But DEA cannot have it both ways: Just like 80% of drivers cannot be above-average drivers, stores that accounted for an allegedly disproportionate amount of Cardinal Health's sale of oxycodone cannot also reflect the risk of diversion posed by Cardinal Health's other—differently situated—customers. Indeed, DEA's own data on purchases of oxycodone by Florida pharmacies confirms that Cardinal Health's current customers pose no obvious risk of diversion: Between 2008 and 2011, the average distribution of oxycodone by Cardinal Health to its Florida pharmacy customers (other than the four at issue here) was invariably at least 45% *lower* than the state-wide average purchases of oxycodone by Florida pharmacies. *See* Opp., Att. 4, at 2-5 (providing underlying data). There is thus no support for DEA's attempt to use the four pharmacies at issue in this case as a proxy for the diversion risk posed by Cardinal Health's *current* customers.²

C. DEA's Own Four-Year Delay Confirms That Cardinal Health Poses No "Imminent Danger"

DEA's own delays cast considerable doubt on DEA's purported need to short-circuit the normal administrative process, which is currently scheduled to commence less than two months from now, on April 3, 2012. *See* Moss Decl., Ex. A. As the Fifth Circuit observed in an ISO case, "[g]enuine apprehension of *imminent* danger to the public health and safety could reasonably have been expected to cause prompt notice and an equally prompt hearing." *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 829 (5th Cir. 1976) (emphasis added). Here, DEA

² Even assuming that DEA could reasonably have "ma[de] a broader conclusion" about Lakeland's anti-diversion controls based solely on the volume of sales to four pharmacies, Opp. 25, DEA first would have had to consider—and explain away—evidence adverse to its ultimate conclusion. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 2887 (1983). But, in the ISO, the DEA did not consider the substantial evidence that supported the effectiveness of Cardinal Health's anti-diversion controls, such as the hundreds of pharmacies Cardinal had cut-off to avoid diversion and Cardinal's substantial investment in its anti-diversion program.

apparently based its purported “imminence” conclusion on an “investigat[ion] [of] Lakeland’s distribution of oxycodone” dating back to “October 2008,” Opp. 1, and on years-old aggregate sales data from 2008, 2009, and 2010 (in addition to 2011), Moss Decl., Ex. A, at 2-3. How data from as far back as 2008 can possibly show that Cardinal Health presented an “imminent threat to the public health or safety” in February 2012, DEA does not say. Nor does DEA explain why it did not act sooner (in 2008, 2009, or 2010) if, as the agency claims, those data—which DEA receives monthly—prove that Cardinal Health’s continued registration posed an *imminent* threat.

Moreover, DEA fails to offer a reasonable explanation for why it waited more than three months after executing its administrative warrant (on October 25, 2011) before serving the ISO (on February 3, 2012). Virtually all the factual allegations contained in the ISO were known to DEA when it issued the warrant. If, on February 3, 2012, these facts alone showed an *imminent* threat to the public health or safety, then presumably these same facts would have shown an imminent threat on October 25, 2011. Yet apparently the threat in October was not so imminent as to prevent DEA from taking what it calls (at 29) “a comparatively short delay” before suspending Cardinal’s registration. Opp. 29. Given that judgment, DEA cannot explain why the threat to the public health and safety is *now* so imminent that DEA cannot tolerate a similar “comparatively short delay” so as to provide Cardinal Health due process.

Relying on two district court cases, DEA attempts to dismiss the significance of its delays here. Those cases, however, underscore how inexplicable DEA’s delay was in this case. In *United Prescription Servs. v. Gonzalez*, 2007 WL 1526654, *4 (M.D. Fla. 2007), the court agreed that DEA appropriately delayed serving an ISO to permit “ongoing negotiations with [registrant’s] counsel.” That stands in stark contrast to the situation here, where Cardinal Health’s offers to meet with DEA officials to discuss DEA’s concerns have been rebuffed. *See*

Ex. C, Moss Decl. And in *Neil Laboratories v. Ashcroft*, 217 F. Supp. 2d 80, 87 (D.D.C. 2002), because DEA “suspected [the registrant] of being an active participant in the chain of production for methamphetamine,” the court found DEA’s delay “justified by [its] ongoing criminal investigation.” Delaying civil enforcement efforts to avoid interfering with an active criminal investigation is a common and accepted practice, but it is not relevant here.³

D. DEA Cannot Support The ISO With *Post Hoc* Rationalizations Set Forth For The First Time In Litigation

DEA has effectively conceded that the ISO does *not* provide a basis for DEA’s conclusion that the continued registration of the Lakeland facility somehow presents an imminent danger to the public health or safety. See ECF No. 13 at 1 n.1 (“DEA offers Mr. Rannazzisi’s testimony *to explain the basis for DEA’s conclusion* that Cardinal failed to ‘maintain effective controls against the diversion of controlled substances.’” (emphasis added)); ECF No. 10 (requesting leave to introduce testimony regarding “the basis for DEA’s February 3, 2012 [ISO] issued to ... Cardinal Health.”). DEA thus improperly devotes a significant portion of its opposition brief to new proposed rationales for its ISO.

It is a bedrock principle of administrative law that, where an agency provides a “contemporaneous explanation of [its] decision ... [t]he validity of the [agency’s] action must ... stand or fall on the propriety of th[e] finding[s]” that appear in the decision. *Camp v. Pitts*, 411 U.S. 138, 142, 93 S. Ct. 1241, 1244 (1973) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 63 S. Ct. 454 (1943)). And DEA’s own regulations make clear that, in issuing an ISO, DEA must provide its “statement of ... findings regarding the danger to public health or safety” in the “order of

³ DEA suggests that it has been delayed because Cardinal has not provided certain “compliance-related communications.” Opp. at 28. But Cardinal Health told DEA its anticipated production schedule and DEA raised no objection. See Declaration of Delia A. Stubbs ¶¶3-4.

immediate suspension” itself. 21 C.F.R. §1301.36(e). *Cf. id.* §1301.37(c) (inapplicable regulation governing OSC proceedings cited by DEA). Thus, it is the rationale contained in the ISO—not *post hoc* rationalizations by DEA’s personnel—upon which the ISO must stand or fall in this action. *See State Farm*, 463 U.S. at 50 (“Courts may not accept ... counsel’s post hoc rationalizations for agency action.” (citing *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 246 (1962))); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419, 91 S. Ct. 814, 825 (1971) (“[P]ost hoc rationalizations” are “an inadequate basis for review” of agency action (internal quotation marks omitted)).

In its Opposition, DEA makes no effort to defend its development of new rationales and new evidence in litigation. In a prior procedural filing, however, DEA made a perfunctory argument that “[a] suspension issued pursuant to 21 U.S.C. §824(d) by definition predates an administrative hearing” and that “[p]rior to such hearing—which commences the administrative process—there obviously can be no administrative record.” ECF No. 10 at 1. But an ISO is itself an agency action, which is undisputedly reviewable in court, where the ISO may be “dissolved by a court of competent jurisdiction.” 21 U.S.C. §824(d). DEA offers no reason why it should be exempted from developing a sufficient administrative record in support of its decision to issue an ISO.

Instead, DEA relies principally on a footnote in the district court decision in *KeySource Medical, Inc. v. Holder*, 2011 WL 3608097, *4 n.2 (S.D. Ohio Aug. 16, 2011). But in that case, DEA offered its evidence “to respond to arguments raised by [plaintiff].” *Id.* Here, the purported rationale advanced by DEA is that it “offer[s] testimony explaining why DEA took the action that it did.” ECF No. 13 at 2. In any event, the Ohio district court’s decision cannot displace standard administrative law principles applied in this jurisdiction. *See Community for*

Creative Non-Violence v. Lujan, 908 F.2d 992, 998 (D.C. Cir. 1990) (Sentelle, J., joined by Ginsburg, R.B., J and Thomas, J.) (“The use of an affidavit by the agency decisionmaker was manifestly inappropriate for a case alleging only violations of the [APA]. The affidavit ... added nothing—it either duplicated the record and was thus unnecessary or it added to the record and was thus beyond the record and of no use to the Court’s consideration of the APA claims, which must be based on the record, even in review of an informal proceeding such as this.”). It is thus clear that the ISO must rise or fall on the assertions set forth in it.

DEA does not attempt to—and indeed cannot—defend the validity of its action solely on the basis of the relevant “contemporaneous explanation”—i.e., the ISO itself. *Pitts*, 411 U.S. at 142, 93 S. Ct. at 1244. Instead, it offers a litany of *new* rationales (along with declarations by DEA officials and 48 exhibits). For example, DEA improperly raises (at 16-17) allegations it made in 2007 about events that allegedly occurred as early as 2005 that did not form the basis for the ISO. Also impermissible is DEA’s *post hoc* reliance on the history of Cardinal Health’s sales to, and oversight of, the four pharmacies named in the ISO. *See* Opp. 18-24. As explained below, *see infra* Part I.E, these assertions are wrong. But they fail for a more fundamental reason: DEA did not rely on them when issuing its “contemporaneous explanation” of the immediate suspension. *See Pitts*, 411 U.S. at 142, 93 S. Ct. at 1244.⁴

E. DEA’s *Post Hoc* Rationalizations Fail On Their Own Terms

Even on their own terms, DEA’s *post hoc* rationalizations do not address *imminent* harm and thus provide no basis for sustaining the ISO. Rather, they pertain to past conduct and relate to sales to the four pharmacies named in the ISO. As explained above, allegations of this sort do

⁴ DEA cannot avoid its obligations under both the APA and the applicable regulation, 21 C.F.R. §1301.36(e), by including boilerplate language in the ISO indicating that the ISO is a “non-exhaustive summary of facts.” *See* Opp. 25.

not show imminent danger. The rationalizations offered by DEA are also in numerous respects incomplete and incorrect. Rather than recite all those errors here, Cardinal Health refers the Court to Mr. Moné's Supplemental Declaration. Set forth below, however, are a few examples.

The 2007 Allegations. DEA implies that the current ISO is an extension of the events of 2007. That is not correct. In 2007, DEA alleged that Cardinal Health had sold substantial quantities of hydrocodone to "rogue Internet pharmacy websites." *E.g.* Opp., Att. 8, at 2. According to DEA, Internet pharmacies drew their customers from websites that connected the customers with unknown doctors, who issued prescriptions on the basis of little or no medical examination and no valid doctor-patient relationship. *See* Am. Moné Decl. ¶ 27(b). That sort of diversion could be identified by a distributor. *See* Supplemental Declaration of Michael A. Moné ¶ 2 ("Moné Supp. Decl."). The allegations in the ISO—involving sales to legitimate pharmacies like CVS—are much different. In these circumstances, it is extremely difficult for wholesalers to discern diversion. *See* Am. Moné Decl. ¶26; Moné Supp. Decl. ¶ 3.

DEA's suggestion (at 11-13) that Cardinal Health failed to disclose the allegations regarding distributions to Internet pharmacies is baseless. That precise issue was discussed at the TRO hearing. *See* TRO Hr'g. Tr. 10:1-11 (Attachment 1) ("This earlier event that you referenced and DEA references in their order did that involve these four stores?" "No, Your Honor, it dealt I believe principally with Internet pharmacies. That was addressed back then. ...") "Are they still involved in the Internet process?" "No, Your Honor."). In addition, Cardinal Health devoted an entire section, on pages 6 and 7 of its TRO brief, to that issue; discussed the issue in the declaration of Michael Moné (¶¶ 27(a) & (b)); and attached the 2008 MOA (ECF No. 3-15) as well as the ISO (ECF No. 3-4), which also referenced the MOA.

Cardinal Health's Suspicious Order Monitoring System. Mr. Moné presented Cardinal Health's SOM system to DEA officials including Barbara Boockholdt, Chief of the Regulatory Section in DEA's Office of Diversion Control, in early 2009. Am. Moné Decl. ¶ 28; Moné Supp. Decl. ¶¶ 4-5. Staff at Lakeland presented the system to DEA officials again during a routine audit of that facility in May 2010, and the officials found it compliant. Butler Decl. ¶ 3. Cardinal Health repeatedly told Ms. Boockholdt that Cardinal Health does not conduct on-site inspections of chain pharmacies and relies on a chain's corporate investigators to perform that function. Am. Moné Decl. ¶ 29; Moné Supp. Decl. ¶ 5 & Ex. 5. Despite these multiple contacts, DEA notes only a single conversation Mr. Moné had with Michael Arpaio, Rannazzisi Decl. ¶ 59. And DEA does not mention that immediately after that conversation, Mr. Moné talked to Mr. Arpaio's supervisor, Ms. Boockholdt, who raised no objection. Moné Supp. Decl. ¶¶ 8-9; *see also* Am. Moné Decl. ¶ 29; Moné Supp. Decl. ¶¶ 4-5.

Cardinal Health's Policies. DEA also suggests that Cardinal Health deviated from its SOM policies. Rannazzisi Decl. ¶ 81(a); Carter Decl. ¶¶ 10, 18. But DEA has misstated those policies. Moné Supp. Decl. ¶ 18. Cardinal Health's policy, about which it informed DEA as early as 2009, was that if a customer's order could not be filled because it was suspicious, Cardinal Health would terminate controlled-substance sales to the customer and report the termination to DEA. Moné Supp. Decl. ¶¶ 20-21. Accordingly, while Cardinal Health made few suspicious order reports, it has terminated sales to over 315 pharmacies since January 1, 2009. Am. Moné Decl. ¶ 23.⁵

The Four Florida Pharmacies. With respect to the specific pharmacies named in the ISO, DEA also mischaracterizes the record. For example, according to DEA, Gulf Coast Pharmacy

⁵ Cardinal Health has recently, in an abundance of caution, revised its policies to require reporting of orders as suspicious in more circumstances. Moné Supp. Decl. ¶ 22.

should have raised Cardinal Health's suspicions in 2010, when, DEA says, a Cardinal Health investigator recommended reporting the pharmacy to DEA. Carter Decl. ¶30(d). But the investigator simply wanted to ask DEA for information DEA did not have. Moné Supp. Decl. ¶ 33(b). Instead, Cardinal Health investigated the issue itself and its concerns were allayed. *Id.*

More fundamentally, DEA's argument, that sales to the named stores, and especially to the Sanford CVS stores, were so high that only an ineffective SOM system could have overlooked a diversion risk, is nothing more than statistical manipulation. DEA says Cardinal Health distributed to the Sanford stores enough oxycodone for a city eight times as large. Rannazzisi Decl. ¶¶ 77-78. An equally plausible estimate would find that Cardinal Health distributed enough oxycodone to provide people in the surrounding county—of whom there are about 422,000, not just the 53,700 living in the city itself—with 7.9 doses per year. Moné Supp. Decl. ¶¶ 11-15. That is about four times *less* than the average rate of oxycodone sales in Florida (a rate that DEA does not disclose is much higher than the rates from other States, such as Michigan, on which DEA's specious "eight times" estimate is based). Similarly, DEA says Cardinal Health's oxycodone sales to these stores were abnormally large compared to Cardinal Health's average pharmacy customer. Opp. 18. But the CVS pharmacies named in the ISO are both large-volume businesses, Am. Moné Decl. ¶ 54, among the largest pharmacies that Cardinal Health supplies. It should hardly be surprising that they represent a large proportion of Cardinal Health's oxycodone sales.

Mallinckrodt's Inquiry. As another example, DEA claims that at a September 30, 2011 meeting, Mallinckrodt (a major oxycodone manufacturer) forced Cardinal Health to conduct immediate on-site inspections of 40 of its top oxycodone purchasers. Rannazzisi Decl. ¶ 64. The basis for this assertion is unclear, because no DEA officials were present at the meeting.

Am. Moné Decl. ¶56. In any event, the assertion is false. *See* Moné Supp. Decl. ¶ 34. DEA, moreover, does not mention that Cardinal Health terminated sales to Caremed even before Mallinckrodt brought that pharmacy up. *Id.* ¶ 35.

DEA's Refusal To Assist. Finally, DEA's conduct undercuts its excuses for not providing Cardinal Health with information about potential diversion by its pharmacy customers. Cardinal Health has promised to terminate any pharmacy that DEA identifies as a likely diversion risk. Moss Decl., Ex. D; Am. Moné Decl. ¶35. DEA suggests it cannot give Cardinal Health such information without violating the due process rights of pharmacies. Rannazzisi Decl. ¶ 40. But on July 7, 2011, Ms. Carter told Mr. Moné to investigate a specific pharmacy in Alaska. Moné Supp. Decl. ¶ 10. Cardinal Health has also asked for data, derived from ARCOS reports, on how much oxycodone pharmacies are purchasing. Am. Moné Decl. ¶35. DEA claims it cannot reveal data derived from ARCOS without violating commercial confidences. Rannazzisi Decl. ¶¶ 39-40. Yet in responding to Cardinal Health's motion, DEA filed in open court exactly the kind of ARCOS-derived data that would have been immensely helpful to Cardinal Health's anti-diversion program: aggregate annual data on other distributors' oxycodone sales to pharmacies in the Sanford area. Opp., Att. 17.

II. CARDINAL HEALTH AND ITS CUSTOMERS WILL SUFFER IRREPARABLE HARM IF A PRELIMINARY INJUNCTION IS NOT ISSUED

This Court correctly concluded when it granted the TRO "that Cardinal Health w[ould] likely suffer irreparable harm from continued suspension of its [DEA] registration." Dkt. No. 4 at 1. As Cardinal Health explained in its opening memorandum, the Lakeland facility supplies thousands of health care providers that require prompt delivery of controlled substances to serve patients with critical needs. PI Mem. 6, 12. The ISO would significantly disrupt Cardinal Health's supply chain, resulting in delays in treatment for legitimate patients

already facing drug shortages. *Id.* 12-13; TRO Order (ECF. No. 4 at 2). This, in turn, would cause severe and irreparable harm to Cardinal Health's reputation for reliability and to its ability to maintain and attract customers. PI Mem. 29-30. Many customers would redirect orders to other wholesale distributors, resulting in a serious and permanent loss of revenue and customers for the Lakeland facility. *Id.* The rerouting of controlled substances required by the ISO would require a major expenditure of time and effort. *Id.* at 30. All of these damages, moreover, would be unrecoverable in light of sovereign immunity. The evidence of imminent harm to the company is more than sufficient to meet Cardinal Health's burden of demonstrating that "irreparable injury is *likely* in the absence of [a preliminary] injunction." *Winter v. National Resources Defense Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original).

A. DEA questions (at 33) whether the ISO would actually cause any distribution delays. It cites, however, no evidence contrary to the declaration of Jon Giacomini, Cardinal Health's President of U.S Pharmaceutical Distribution, in which he explains that the ISO "will cause distribution delays of controlled substances to Cardinal Health's customers in Florida." Giacomini Decl. ¶ 4. DEA suggests that Cardinal Health need not service any Florida customers from its Denver distribution facility. *Id.* But, as explained in Mr. Giacomini's Supplemental Declaration, certain shipments must be made from the company's Denver facility in order to comply with Florida's unique "pedigree" requirements. *See* Supp. Giacomini Decl. ¶ 6. The fact that a press report paraphrasing Cardinal Health's CEO mentioned only the Mississippi facility, *see* Opp. 33, is no basis to question Mr. Giacomini's sworn declaration. DEA, moreover, offers no reason to doubt that shipments to Florida from the other two alternative facilities (Greensboro and Jackson) will result in delays as well.⁶ Mr. Giacomini explained that these distribution delays

⁶ DEA's contention that Cardinal Health could deviate from normal shipping protocols and

will cause some customers to leave Cardinal Health. Giacomini Decl. ¶¶ 20-22. DEA provides no reason to question this conclusion.

B. Alternatively, DEA contends (at 33-24) that the harm to Cardinal Health is insufficient because it will not “threaten[] the survival” of Cardinal Health’s business. This, however, is not the applicable standard where, as here, sovereign immunity bars an injured party from recovering monetary damages. The D.C. Circuit has repeatedly explained that the “economic” harm principle cited by DEA (at 32, 34) applies to *recoverable* economic losses. *See, e.g., Virginia Petroleum Jobbers Ass’n v. FPC*, 259 F.2d 921, 925 (1958) (“The key word in this consideration is *irreparable*.”); *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1295 (D.C. Cir. 2009) (“[R]ecoverable economic losses are not considered irreparable.” (internal quotation marks omitted) (emphasis added)); *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (“*Recoverable* monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant’s business.” (emphasis added)).

Decisions from this Court have accordingly recognized that economic losses constitute irreparable harm “where, as here, the plaintiff in question cannot recover damages from the defendant due to the defendant’s sovereign immunity.” *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (Walton, J.); *see also Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) (quoting *Feinerman*, 558 F. Supp. at 50–51); *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010); *Hoffmann-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978).

provide for “expedited delivery” in “time sensitive” situations disregards the fact that hospitals often have “just-in-time” inventory levels and thus frequently require “time sensitive” shipments. *See Giacomini Decl.* ¶ 11.

DEA cites *National Mining Association v. Jackson*, 768 F. Supp. 2d 34 (D.D.C. 2011), but that case quoted decisions holding that loss of income is irreparable *per se* where sovereign immunity precludes recovery and simply held that the usual certainty and imminence requirements continue to apply in those circumstances. *See id.* at 52-53 (internal quotation marks omitted). DEA also relies on *Air Transport Association of America, Inc. v. Export-Import*, 2012 WL 119557 (D.D.C. Jan. 13, 2012), but the Court there held only that the relevant loss must be “significant.” *Id.* at *7. The quote from *National Shooting Sports Foundation, Inc. v. Jones*, No. 11-1401, 2011 WL 3875241, at *3 n.5 (D.D.C. Sept. 2, 2011), similarly states just that the harm must be “certain and great”—not that it must threaten the movant’s survival.⁷

Here, there can be no dispute that the harm to Cardinal Health would be both unrecoverable and “great.” As explained in the Supplemental Declaration of Mr. Giacomini, the 2007 suspensions of four facilities caused Cardinal Health to lose “roughly \$1 billion of lost sales” on an annualized basis. Supp. Giacomini Decl. ¶ 3. Additionally, Cardinal Health estimates that just one portion of the losses due to the Lakeland ISO—decreased sales to retail independent pharmacies *that remained with Cardinal Health*—amounted to approximately \$100 million. *Id.* ¶ 4.⁸ Moreover, it is likely that an ISO of the Lakeland distribution center today would have an even greater impact than the 2007 Lakeland ISO did, because, unlike in 2007, Cardinal Health’s principal competitors are not currently facing disruptions in their distributions to Florida. *See* Supp. Giacomini Decl. at ¶5.

⁷ In *Coalition for Common Sense in Government Procurement v. United States*, 576 F. Supp. 2d, 162 (D.D.C. 2008), the Court ultimately rested its decision on the movant’s “failure to demonstrate anything more than de minimis economic harm.” *Id.* at 170.

⁸ DEA tries to minimize the impact of a suspension on the Lakeland facility by discussing financial figures for Cardinal Health as a whole. In fact, however, the DEA registration at issue applies specifically to the Lakeland facility, and the ISO is directed only at that facility.

C. Additionally, courts routinely recognize that harms like the loss of customers, loss of reputation and goodwill, and an inability to attract new customers can constitute irreparable harm. *See* PI Mem. 29 (citing cases); *see also, e.g., Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 77-78 (D.D.C. 2001) (finding irreparable harm from “the loss of [plaintiff’s] customers and by the possibly permanently damaged relationships with its customers”); *George Washington University v. District of Columbia*, 148 F. Supp. 2d 15, 18 (D.D.C. 2001) (same, from loss of reputation); *McVeigh v. Cohen*, 983 F. Supp. 215, 221 (D.D.C. 1998) (same); *see also Dominion Video Satellite, Inc. v. EchoStar Satellite Corp.*, 269 F.3d 1149, 1157 (10th Cir. 2001); *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994). Indeed, damages—including economic losses—that are “of such nature as to be difficult, if not incapable, of measurement” also constitute irreparable harm. *See, e.g., Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952). The loss of customer goodwill and prospective customer relationships often falls into this category. *See, e.g., Foodcomm Intern. v. Barry*, 328 F.3d 300, 304 (7th Cir. 2003); *Basicomputer Corp. v. Scott*, 973 F.2d 507, 512 (6th Cir. 1992).⁹ Under these principles, the injuries Cardinal Health will suffer absent a preliminary injunction unquestionably constitute irreparable harm. *See* PI Mem. 29-30.¹⁰

⁹ DEA reads *Sampson v. Murray*, 415 U.S. 61 (1974), as holding that damage to reputation does not constitute irreparable harm. But that case involved termination of a federal employee, an action that the Supreme Court concluded could be enjoined only in the most extraordinary of circumstances. *See id.* at 83-84, 92 n.68. Although the Court found the claim of reputational harm in that case insufficient, it did not purport to establish a generally applicable rule that reputational harm is not irreparable. *See id.* at 92 n.68.

¹⁰ In addition, DEA does not squarely address the harm to Cardinal Health that would be caused by requiring it to alter its supply lines and re-route controlled substances through alternative distribution facilities. *See* PI Mem. 30.

III. THE BALANCE OF THE HARDSHIPS ALSO FAVORS ISSUANCE OF A PRELIMINARY INJUNCTION

For all of the reasons set forth above, the ISO would cause irreparable harm to Cardinal Health. By contrast, requiring DEA to follow the normal procedures for considering whether to revoke Cardinal Health's registration will impose no harm on the agency. As explained above, Cardinal Health's continued registration imposes no "imminent danger to the public health or safety." 21 U.S.C. §824(d). Moreover, DEA will suffer no more harm waiting for an administrative hearing to be held in the next couple of months than it did during the *years* it stood idly by watching actions by Cardinal Health that it now—for the first time—contends give rise to *imminent* danger. It simply is not credible for DEA to claim harm in the circumstances of this case. DEA's apparent real concern—that its power to immediately suspend distributors may be "gutted" (at 38) if courts rigorously adhere to the statutory standard set forth in §824(d)—is simply not the kind of harm cognizable in the balancing before the Court.

IV. THE PUBLIC INTEREST WILL BE SERVED BY ISSUANCE OF A PRELIMINARY INJUNCTION

Enjoining the ISO would also serve the public interest. The ISO threatens to disrupt delivery of needed medications for countless critically ill patients, *see* PI Mem. 12-13, a concern which DEA nowhere addresses. Rather, DEA appears to contend (at 40) that enjoining the ISO somehow would "effectively allow Plaintiffs to opt out of the administrative process Congress has designed." But it is certainly not Cardinal Health that is trying to avoid the administrative process set forth in the CSA. Cardinal Health seeks an injunction to prevent *DEA* from needlessly depriving the company of the procedural safeguards applicable to order to show cause proceedings before DEA in the normal course. *See* 21 U.S.C. §824(c). *Cf.* Opp. 39 (accusing Cardinal Health of

“disregarding the administrative process altogether”). Cardinal Health is asking for nothing more than the opportunity to participate in a meaningful “administrative process”—as opposed to being immediately suspended without notice or an opportunity to be heard, based on an administrative record that DEA appears to be trying to construct in the course of this litigation.

In addition, DEA labels speculative Cardinal Health’s assertion that its anti-diversion program is one of the best in the country. *See* Opp. 40. But that is how DEA’s own inspectors have characterized the system. *See* Am. Moné Decl. ¶ 29. Indeed, in the period following the 2008 MOA, Cardinal Health’s system has resulted in the suspension of numerous pharmacies whose registrations have not been suspended by DEA. PI Mem. 8-9. The strength of Cardinal Health’s system in 2007, *see* Opp. 41, is not at issue here. Finally, DEA suggests (at 39) that an injunction is necessarily contrary to the public interest unless Cardinal Health can demonstrate that DEA acted in “bad faith” or was grossly negligent. But DEA cites no authority for that unlikely proposition.

CONCLUSION

For the foregoing reasons and for the reasons set forth in Cardinal Health’s Motion for Preliminary Injunction, Cardinal Health respectfully requests that this Court issue a preliminary injunction that prevents DEA from enforcing the ISO pending final judgment in this action.

Respectfully Submitted,

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